

## **DETAILED ACTION**

### ***Status of the Application***

Receipt is acknowledged of the Power of Attorney Notice filed on 04/05/04.

The previous Non-Final Office Action filed 07/11/02 has been vacated. The following are the new grounds of rejection:

Claims 153-158 are pending in this action. Claims 1-152 have been cancelled.

Claims 153-158 are rejected.

### ***Introductory Remarks***

The immediately preceding examiner is now the SPE of an art unit in a different Technology Center. The instant examiner recognizes that this case has been pending for a very long time and offers sincere apologies for the length of time. The file was apparently lost for several years, changed examiners and spent time being evaluated for interference at the Board of Patent Appeals and Interferences. According to a note from APJ Mike Tierney to SPE Cecilia Tsang on August 12, 2003, the claims submitted in the instant application appear to lack written description (that is, constitute new matter) and the undersigned examiner agrees with this assessment. Thus, the instant Office action is necessary. Again, the amount of time is regretted.

### ***Claim Rejections - 35 USC § 112, First Paragraph, Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact

terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 153-155 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. A review of the instant specification indicates that support cannot be established for the ranges of iodine recited in claims 153-155. Namely, support has not been established for the "greater than 20% to about 70% iodine" (as in claim 153); "greater than 20% to about 60% iodine" (as in claim 154) and "about 25% to about 50% iodine" (as in claim 155). The instant specification shows varied amounts of iodine employed in the Examples. Example 1 at page 43 demonstrates 60.00 grams of iodine and 40 grams of potassium iodide, but provides no information as to the percentage of iodination this might represent. Percentages of iodine are disclosed on page 72 of the specification, however, the instant ranges of iodine of claims 153-155 are not disclosed in the specification. Applicant is kindly requested to identify where in the specification support can be located for the instant iodine ranges of claims 153-155. At present, the specification fails to support the recited ranges (of claims 153-155).

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 153-155 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 153-155, the phrase "(by weight)" renders the claim indefinite because it is unclear whether the limitation(s) provided in parentheses is part of the claimed invention or whether the limitation has been provided merely for exemplary purposes only.

Clarification is requested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 153-158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (U.S. Patent No. 4,238,477).

Lambert et al. teach a demand for a disinfectant resin comprising strong base anion exchange resin beads and elemental iodine. The resin is in the iodide form and the iodide is applied with a water carrier which is recycled in contact with the resin and the stoichiometric amount of iodine to form the desired polyiodide. A homogeneous product of predetermined polyiodide content is obtained (see Abstract); (column 1, line 58 – col. 2, line 20).

An example of a resin disclosed is DOWEX-X8 (col. 3, lines 41-45).

Lambert et al. do not teach “a method for disinfecting a biological fluid (claim 153) and body fluid (claims 156-158)” and does not teach the amounts/ranges of the anion exchange resin relative to the total weight of the iodinated resin. However, it is the position of the Examiner that since the prior art clearly teaches a demand for a disinfectant resin comprising strong base anion exchange resin beads and elemental iodine – the same components as claimed by Applicant; the product of Lambert et al. would amply provide for the desired disinfection capabilities and “methods of disinfecting” as instantly desired by Applicant, absent a showing of evidence to the contrary. The prior art’s product entails a demand for a disinfectant resin comprising the elements and features as instantly claimed and thus, the particular use of the product, i.e., method of disinfecting a biological and/or body fluid as currently recited, would be possible based on the product disclosed by Lambert et al., which is clearly applicable

for disinfecting purposes. As a result, the instant method of disinfection would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made given the teachings of Lambert et al.

With respect to the amounts/ranges of the anion exchange resin relative to the total weight of the iodinated resin, the amounts would be such that the iodine-loaded resin would be capable of disinfecting the medium in which it is placed. The resin in Lambert et al. is loaded according to milli-equivalent (meq) capacity of the resin for optimal disinfection (col. 3, lines 15-45). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. It is considered to be well within the ordinary level of skill in the art to determine the appropriate proportions. Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable ranges or percentages of the anion exchange resin through routine or manipulative experimentation, to obtain the best possible results, as these are variable parameters attainable within the art. Even further, no unexpected or superior results have been observed in the instant amounts/ranges of the anion exchange resin claimed. The prior art clearly teaches a demand for a disinfectant resin comprising strong base anion exchange resin beads and elemental iodine; the same elements and features as presently claimed. Hence, the instant invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Lambert discussed above.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 156-158 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-12 of prior U.S. Patent No. 6,899,868. This is a double patenting rejection.

### ***Pertinent Art***

*Fina et al.* (U.S. Patent No. 4,999,190) (March 12, 1991) is cited as of interest.

### ***Conclusion***

No claims are allowed.

### ***Correspondence***

Any inquiry concerning this communication or communications from the previous examiners should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday from 9:30 to 3:30.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert A. Wax/  
Supervisory Patent Examiner, Art Unit 1615